DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Best Theratronics Limited
% Mr. Mike de van der Schueren
Quality and Regulary Manager
413 March Road
Ottawa, Ontario K2K 0E4
CANADA

November 13, 2014

Re: K142219
Trade/Device Name: Gammabeam 100
Regulation Number: 21 CFR 892.5750
Regulation Name: Radionuclide radiation therapy system
Regulatory Class: II
Product Code: IWB
Dated: October 15, 2014
Received: October 15, 2014

Dear Mr. de van der Schueren:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K142219

Device Name: GammaBeam 100

Indications For Use:

A Cobalt Teletherapy unit is a device by which gamma radiation is delivered for the treatment of cancer under the direction of health care professionals in a radiation therapy clinic.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

510(k) SUMMARY

Date Summary Prepared	October 14, 2014
Submitted by	Best Theratronics 413 March Road Ottawa, Ontario K2K 0E4 Canada Tel. (613) 591-2100 Fax. (613) 592-5680
Contact Person	Mr. Mike de van der Schueren Quality & Regulatory Manager
Trade Name	GammaBeam 100
Common Name	Cobalt Teletherapy Device
Classification Name	Radionuclide Radiation Therapy System
Legally Marketed Predicate Device	Theratron Phoenix (K863180)
Device Classification	Class II, 21 CFR 892.5750
Product Code	IWB

Description of Device

The GammaBeam 100 is a radiotherapy treatment unit with a cobalt-60 radiation delivery system. The device consists of a source head, collimator, gantry, main frame, base, controls and a pendulum or beam-stopper style counterweight. The design of this device is substantially equivalent to predicate device Theratron Phoenix.

Intended Use of Device

A Cobalt Teletherapy unit is a device by which gamma radiation is delivered for the treatment of cancer under the direction of health care professionals in a radiation therapy clinic.

The indications/intended use of the modified device, as described in the labeling, has not changed as a result of the modifications.

Summary of Technological Characteristics

The GammaBeam 100 is substantially equivalent to the predicate device (K863180).

This GammaBeam 100 includes several changes to the design of Phoenix teletherapy unit.

- an updated control system
- new independent jaws collimator
- new covers

Changes are made due to obsolescence of many components in the existing Phoenix control system as well as to achieve compliance with current regulatory standards.

Usability is being improved by adding functions relevant to contemporary cancer treatment techniques and removing those that are not.

The major components of the Theratron Phoenix, including the head, gantry, main frame, base, and pendulum/beam stopper counterweight have had minor modifications to accommodate the above changes.

There are no changes to the mechanical structure or radiological shielding of the head.

The irradiation source and radioactivity of the cobalt-60 source remains unchanged as does the source drawer mechanism.

The control system has been designed to meet the same intended use as the current model.

Safety & Effectiveness

The safety of the GammaBeam 100 is equivalent or better than the predicate device.

In terms of safety, the GammaBeam 100 is designed to comply with

- IEC 60601-1-2: Edition 3.0 2007-03 Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests (Appendix Q)
- IEC 60601-1: Edition 3.0 2005 + CORR. 1 (2006) + CORR. 2 (2007) Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (Appendix R)
- EN 60601-2-11 (2004) Medical electrical equipment – Part 2: Particular requirements for the safety of gamma beam therapy equipment
- EN 61217 (2011) Radiotherapy equipment – Coordinates, movements and scales

The performance of the device was tested against a set of functional specifications in an environment that simulated, as much as possible, the actual operating environment. Validation testing demonstrated that the device is as safe and effective as the predicate device.